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To: NCIC HPV@EPA

11/20/2003 01:26 PM

Subject: Environmental Defense comments on 5,5-Dimethylhydantoin (CAS# 77-71-4)

---- Forwarded by Anh Nguyen/DC/USEPA/US on 11/20/2003 01:33 PM -----

Richard Denison@environmentaldefense.org on 11/20/2003 12:19:13 PM

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Subject: Environmental Defense comments on 5,5-Dimethylhydantoin (CAS# 77-71-4)

(Submitted via Internet 11/20/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Edwin.L.Mongan-1@usa.dupont.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summaries/test plan for 5,5-Dimethylhydantoin (CAS# 77-71-4).

The American Chemistry Council Brominated Biocides Panel DMH Task Group, in response to the HPV Challenge, has submitted Robust Summaries and a Test Plan for 5,5-dimethylhydantoin (DMH).

This Test Plan contains considerable redundant or unnecessary information that can and should be deleted:

- a 12-page Table of Contents that mostly merely lists references already provided in Appendix B; and
- two pages of explanation in Appendix A of how in general chemical properties and environmental fate are modeled; as this information is not specific to DMH, it should be deleted. [NOTE: Appendix A does provide a table of Physical/Chemical data and a table of Environmental Fate and Ecotoxicity that are appropriate to a discussion of these SIDS elements in a Test Plan, and should be retained in a revised Test Plan.]

The Test Plan narrative is quite brief, consisting only of a structural formula for the chemical, a matrix of SIDS elements versus available data and a very limited description of DMH, its properties and toxicology. While not strictly required, it would be useful for the Sponsor to provide some background information on uses, transport and possible sources of release into the environment or human exposure. In addition, a list of synonyms ought to be provided.

In summary, we find this Test Plan of little use and would recommend that the Sponsor revise it to be more consistent in content and structure with other good examples of Test Plans submitted in response to the HPV Challenge.

In contrast to the Test Plan, the Robust Summaries (Appendix B) are extensive and are presented and described in a well-organized manner. Each of the requested SIDS elements is addressed in order and, in most cases, is supported by a number of recent studies. Data obtained through computer modeling to estimate chemical/physical properties are also appropriately presented. Whereas it is unfortunate that most of the studies cited are not available to the public, most are recent and conducted under GLP, and they are well-summarized. In some of the studies, the purity of the DMH was not determined or not reported; however, in most cases other studies in which DMH purity was given are also cited to address the same SIDS element.

Review of these data indicates DMH degrades rapidly in the environment, has low acute and repeated dose toxicity, low reproductive and developmental toxicity and is not mutagenic in any of several systems. Our review indicates that the only requested SIDS element not adequately addressed is that for toxicity to aquatic plants. According to the Test Plan these data are "considered inconsequential" by the Sponsor to meeting the HPV Challenge because DMH is adequately studied for other species. We do not agree. Whereas it is true that data available for numerous other species indicate this compound is relatively nontoxic to those organisms, none of the other species tested are plants. Many potent herbicides show little toxicity to species other than plants. Thus, in order to complete the requisite dataset, DMH's toxicity to aquatic plants needs to be determined.

In summary, with the exception just noted, extensive data are available for DMH and are well-described in the Robust Summaries presented in Appendix B. However, they are very poorly summarized in the Test Plan. We would recommend the Test Plan be revised to provide more useful information for the general public, as requested in EPA's original HPV Challenge letters to chemical manufacturers and importers.

Thank you for this opportunity to comment.

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